

proper U.S. form, and these amendments include the drafting of new dependent claims directed to certain subject matter eliminated from the original claims pursuant to the requirements of the Examiner. Since the changes to the claims were merely related to placing the claims in proper form and in deleting language deemed objectionable by the Examiner, no new matter has been added to the application. Applicant submits that in light of the present amendments to the claims, the application overcomes the prior rejections of the Examiner and should be in condition for allowance for at least the reasons set forth below.

In the Official Action, the Examiner provisionally rejected Claims 1-48 under the judicially created doctrine of double patenting over claims 1-22 of copending Application No. 08/692,113. Without addressing the merits of this rejection, the rejection has become moot in that Applicant's previously co-pending application Serial No. 08/692,113 has now gone abandoned. A copy of the abandonment notice is attached hereto for the convenience of the Examiner.

In the Official Action, the Examiner rejected Claim 27 under 35 U.S.C. § 101 on the basis that this claim in its original form appeared intended to embrace both a kit and the composition of claim 1. This rejection has now been traversed in that Claim 27 has now been amended to be directed to the kit containing the compounds as now indicated in the amended claim.

In the Official Action, Claims 1, 4, 5, 10, 16, 18-25, 27, 32, 37-39, and 45-48 were rejected under 35 U.S.C. § 112, second

paragraph, on the basis that the claims included terms considered objectionable by the Examiner, including "in particular", "preferably", or "such as." The rejections to these claims have now been traversed in light of the present amendments to these claims which eliminate the language deemed objectionable by the Examiner.

The Examiner also rejected claims 8, 9, and 31 under 35 U.S.C. § 112 on the basis that the structure or the complete chemical name for the compounds should have been provided. However, the Examiner also stated that the designations of the claims were clear and understandable. See Official Action at page 5. In light of this, Applicant submits that these claims in their present form are acceptable under 35 U.S.C. § 112, and Applicant is hesitant to amend the claims at the risk of providing a chemical designation which may not be accurate. However, should the Examiner maintain this rejection, Applicant would be willing to amend the claims in consultation with the Examiner in an effort to come up with acceptable language for these compounds.

In the Official Action, the Examiner rejected Claims 1-48 under 35 U.S.C. § 103 on the basis of the combined teachings of Duffy et al. U.S. Patent No. 5,612,047, the 1995 Postal et al. article, and Skillman et al. PCT application WO 95/33380. The Examiner argued that one of ordinary skill in the art would be motivated to combine these references because they disclosed active agents for use in controlling the same pests on the same hosts, and that in light of these references, it would have been prima facie

obvious to combine the compositions for the purpose of controlling fleas. The Examiner's position is based on the argument that the mere combination of two known active principals, in the present case a phenylpyrazole such as fipronil, and an insect growth regulator such as methopren or pyriproxyfen, is obvious where the aim of the combination is just to make an addition of the individual properties of both active principals. However, for reasons as set forth in detail below, this is not the case. Accordingly, this rejection, insofar as it applies to the claims as amended, is respectfully traversed for at least the following reasons.

In addition to the references cited by the Examiner, which do not disclose or suggest the present invention for reasons as stated below, Applicants are also aware of other prior art references in this field, including European Pat. App. No. 295,117 (copy provided herewith in the accompanying IDS) which states, at page 8, line 3, that examples of pesticidally-active compounds which may be included in the compositions (comprising a fipronil) are . . . teflubenzuron. Teflubenzuron is an IGR. In addition, U.S. Pat. No. 5,567,429 (copy enclosed) discloses the combination of one N-aryldiazol compound being fipronil with an IGR, for example, pyriproxyfen or methopren at a conventional mixing ratio range.

Contrary to the teachings of the prior art, however, the present invention is directed to a composition and process for long-lasting protection against fleas, especially in cats and dogs, where both compounds "A" (for example, fipronil) and "B" (for

example, an IGR) are in fluid vehicles which are acceptable to the animal and suitable for local application on the skin, e.g., as a spot-on or a pour-on. The composition fipronil (the preferred embodiment for compound A) was known to be efficient to control cat or dog fleas. The best known composition and method for that purpose was disclosed by Postal as a mechanical pump spray composition which needs to be applied by spraying the composition over the totality of the dog or cat.

On the other hand, IGR compositions were known to be efficient to control fleas on pets by several varying formulations, the most efficient being a systemic administration of IGR such as methoprene or pyriproxyfen, through oral, parenteral or transdermal routes to obtain an IGR level in the pet's blood that would be sufficient to kill the flea which sucks the blood. This systemic administration is disclosed, for example, in U.S. Patent Nos. 4,973,589 and 5,439,924, copies of which are attached hereto in the accompanying Information Disclosure Statement.

In this regard, none of the prior art references cited by the Examiner are relevant to the present invention because they do not disclose or suggest, either individually or in combination, a composition for long-lasting protection against fleas which employ the compounds of the invention in a fluid vehicle acceptable to the animal and suitable for local application on the skin. For example, the Skillman PCT application is not relevant because it does not disclose or suggest any precise means to control fleas on

pets, much less any composition for local application on the animals such as a spot-on.

Similarly, the Duffy et al. patent is not relevant to the present invention because it only relates to micro-emulsions of an IGR and an adulticide, like pyrethrin, which may be used against fleas by application on the pets in the form of deeps, sprays, or a pour-on. Moreover, Duffy shows that such external application of his formulation secures poor control of fleas with a better control of flea eggs hatching. On the other hand, the Postal reference shows that flea control by fipronil spray can be efficient during the first month, but protection then decreases significantly.

Accordingly, due to the very different pattern of protection related to time, the problem which is addressed by the present invention was to find a composition and a process which would lead to a very high efficacy against adult fleas and eggs and which could afford long-lasting protection against adult fleas and eggs.

Of the prior art references cited by the Examiner or discussed above, U.S. Pat. No. 5,567,429 is the most relevant in that it discloses various compositions combining fipronil with an IGR, but this is done only in a very general way for various uses. More precisely, the examples show to use of an aerosol in examples 1 and 2, a poisonous bait in example 3, and in poisonous baits against cockroaches in test example 1, houseflies in test example 2 and 3, all of which are of no use in the field of control of fleas on pets.

In fact, the sole example in the field of controlling fleas on pets is example 4 which discloses a pesticidal collar for pets containing both N-aryl diazole and IGR. However, polymeric collars are known to allow relatively slow, permanent, and long-term controlled release of the active ingredients, which solves, in an obvious way, the discrepancy between the time-efficiency relationships of both active principals because it secures (at least theoretically) a permanent release of both compounds.

Thus the artisan faced with the problem of long term efficiency of a combination of a compound A and compound B would be motivated by the teaching of this patent to use a collar as a permanent long term release system. This actually teaches away from the present invention and leads the skilled artisan in an opposite direction, i.e., far away from using a local application means such as a spot-on for a long lasting control of fleas by one instantaneous administration to the household animal, as is accomplished by the present invention.

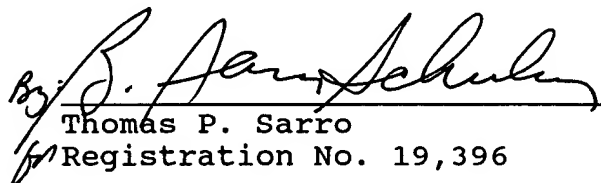
Accordingly, Applicant submits that none of the references cited by the Examiner or provided herewith by Applicant, either singly or in combination, disclose or suggest Applicant's invention as presently claimed, and that the rejection under 35 U.S.C. § 103 on the basis of the cited references is respectfully traversed and should be withdrawn.

Applicant thus submits that in light of the present amendment and arguments set forth above, the claimed invention is patentable over the references cited by the Examiner, and that the application in its present form is in condition for immediate allowance. Such action is earnestly solicited.

Respectfully submitted,
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Date: June 5, 1998

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